UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**MDL 2804**
	)	
	)	**Case No. 1:17-md-2804**
THIS DOCUMENT RELATES TO:	)	
	)	**Judge Dan Aaron Polster**
Applies to All MDL Cases	)	

HIKMA PHARMACEUTICALS PLC'S STATUS REPORT PURSUANT TO ECF NO. 4380

The Court directed Hikma Pharmaceuticals PLC[1] ("Hikma") to submit a status report on three topics. *See* ECF No. 4380 ("Order").

First, the Order asked "how and whether Plaintiffs intend to proceed" against each Defendant. Although Hikma lacks insight into how and whether Plaintiffs ***intend*** to proceed against Hikma, it is Hikma's position that, at a minimum, certain Plaintiffs should not be ***allowed*** to proceed against Hikma, particularly in: (i) cases in which Hikma has *de minimis* market share, and (ii) cases in which Hikma was added between 2019 to 2021 through the amended short form complaint process without any constructive notice or service.

Second, the Order asked whether Hikma is interested or currently engaged in active settlement negotiations and, if interested, whether Hikma prefers to retain an outside mediator or have the Court assist in those negotiations. Hikma is not currently engaged in global settlement

[1] Hikma Pharmaceuticals PLC is the parent company of Hikma Pharmaceuticals USA Inc. (formerly known as "West-Ward Pharmaceuticals Corp."). Hikma Pharmaceuticals PLC was named in the Order, but Hikma Pharmaceuticals USA Inc. is the relevant party in interest for this litigation. As directed by Footnote 1 of the Order and for purposes of this status report only, references to "Hikma" include references to all entities in Hikma's "Defendant Family" that are named in the National Prescription Opiate Litigation.

negotiations but has had success in settlement negotiations and in gaining dismissals in individual actions. Assuming Plaintiffs intend to proceed against Hikma, Hikma would like to discuss a formal mediation, settlement, and/or dismissal process with appropriate members of the Plaintiffs' Executive Committee ("PEC"). Hikma is not opposed to the Court's assistance in settlement negotiations but as an initial matter would prefer to explore whether an outside mediator can achieve a global resolution.

Third, the Order asked Hikma's position on whether and how the Court should conduct bellwether trials, including proposals for potential cases to be named as new bellwether tracks, if any. Hikma does not believe that now is the time to set bellwether trials because it is already party to a number of active state cases across the country. These cases will provide the parties with the opportunity to test their legal theories and claims. Adding bellwethers on top of formalized mediation and the current fulsome docket of litigation would overwhelm a party the size of Hikma and potentially undermine settlement efforts.

Below, Hikma provides a brief overview of its business and its place in this litigation as necessary context for Hikma's responses.

Brief Overview of Hikma's Opioids History

Hikma is a relatively small generic manufacturer with its U.S. headquarters located in New Jersey. Hikma manufactures a variety of injectable and non-injectable products, including medicines that are used to treat patients with COVID-19 and drug addiction. Although Hikma manufactures some of the generic opioid products identified as relevant in litigation pending in this MDL, Hikma did not and does not promote any opioid products, and it did not and does not manufacture, distribute, sell, market, or promote any branded opioid products. As a generic company, Hikma's business is to manufacture products for distributors, competing with other

generic manufacturers based solely on price and availability. To be clear, Hikma, unlike some companies that have manufactured both generic and branded opioids, manufactures only generic opioids and has never promoted any opioids.

Prior to 2016, Hikma manufactured no relevant opioid products: In May 2011, Hikma acquired a unit of Baxter Pharmaceuticals, which manufactured ***injectable*** opioid drug products. These injectable opioids are not properly part of any action currently pending in the MDL. No plaintiff that Hikma is aware of in either state or MDL litigation alleges that injectable opioids (which are administered only in hospital settings by healthcare professionals) have been mis-marketed, oversold, or diverted. In fact, other manufacturers of injectable opioids like Pfizer, Hospira, and Fresenius Kabi have either been dismissed from litigation or were never sued at all. This makes sense because injectable products do not present an opportunity for potential abuse. Injectable opioid products are purchased, safeguarded, and administered only by healthcare professionals in hospitals or surgery settings.[2] For these reasons, Hikma has already obtained a voluntary dismissal of the claims against it relating to injectable opioids in one state litigation where active discovery occurred.

It was not until 2016 that Hikma added Schedule II oral opioid products to its portfolio: Hikma acquired another company that was selling Schedule II generic oral opioid products in 2016. But even with that acquisition, Hikma's portfolio of oral opioid products consists only of generic products that were not subject to the type of marketing misconduct alleged to have resulted in the injuries at issue in these cases. Moreover, a significant portion of Hikma's generic oral

[2] *See, e.g.*, Fentanyl Citrate Injection Principal Display Panel, N.I.H. NAT'L LIBRARY OF MED., https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ce5db1c2-feb1-4ad2-847a-d02e865bd47e&audience=professional ("For slow intravenous use by hospital personnel specifically trained in the use of narcotic analgesics.").

opioid products are addiction therapy products designed, approved, and used to treat opioid dependence or overdose.

Focusing on the remaining relevant opioids, Hikma was a manufacturer of only a very small amount of generic oral opioids. Based on dosage units in available ARCOS data (2006-2014) for the localities that have sued Hikma in this MDL, for example, Hikma had (1) no market share at all with respect to the relevant products in four of those localities, (2) approximately 1% or less of the market share in 30% of those localities, (3) 2% or less of the market share in 66% of those localities, (4) and 5% or less of the market share in 95% of those localities. Hikma's sales and market share have decreased even further since 2014. And, Hikma has been dismissed in state court litigation in South Carolina and federal litigation in San Francisco on the basis of *de minimis* market share.

Topic 1: Whether and How Plaintiffs Intend to Proceed Against Hikma

Although Hikma lacks insight into how and whether Plaintiffs ***intend*** to proceed against Hikma, Hikma respectfully urges that certain Plaintiffs should not be ***allowed*** to proceed against Hikma. For instance, Hikma should not be a defendant in the approximately 95% of cases in which Hikma has less than 5% market share. The Court previously ordered the PEC to produce reports derived from ARCOS data that identify manufacturers with more than 5% market share. *See* ECF No. 1106. The MDL Plaintiffs could "then use this information to amend" or file complaints. *See id.* at 2. The 5% threshold was intended keep defendants with less than 5% market share out of cases. Indeed, the PEC has referred to those defendants with less than 5% market share as "*de minimis*." *See* ECF No. 1077 at 2-3; ECF No. 1350 at 7-8.

Also, in numerous cases, Plaintiffs added Hikma as a defendant to existing cases in 2019 to 2021 without any constructive notice or service to Hikma through the amended short form

complaint process. These "unserved cases" are problematic because the addition of Hikma to the cases violated the Federal Rules and orders of this Court. Moreover, Hikma is mentioned in only one or two paragraphs in most of the complaints. In most (if not all) of these cases, the complaints provide no detail at all regarding the alleged actions Hikma is supposed to have undertaken to contribute to the national opioid epidemic. Hikma has not been subject to any MDL discovery, and in fact was dismissed from the remanded San Francisco case because of its small market share there.

Given these issues and Hikma's *de minimis* market share in these cases, Hikma requests that this Court issue an order similar to the one it issued in connection with selecting litigation tracks for the Pharmacy Defendants—namely, an order allowing Hikma to identify those cases where it has *de minimis* market share in the relevant jurisdictions and directing Plaintiffs in those cases to begin dismissing Hikma with prejudice. *See* ECF No. 3688. Such an order would assist in the efficient resolution of these matters by cutting through potentially months of negotiations to effectuate Hikma's dismissal from cases in which it should have never been named. To this end, Hikma can expeditiously provide Plaintiffs' counsel with a list of cases pending in the MDL in which it has *de minimis* market share.

Topic 2: Whether Hikma Is Interested in Settlement and Status of Settlement Negotiations

Hikma is interested and willing to participate in settlement negotiations. Indeed, Hikma just recently became the first generic manufacturer to reach a settlement-in-principle with the Attorney General of the State of New Mexico. If Plaintiffs intend to proceed with litigation against Hikma, Hikma is open to discuss any process that the PEC might suggest and looks forward to addressing specific options that are proposed. To date, the PEC has not shown an interest in discussing settlement with Hikma. Hikma is not opposed to the Court's assistance in settlement

negotiations but as an initial matter would prefer to explore whether an outside mediator, given sufficient time, can efficiently guide a global resolution.

Topic 3: Whether Bellwether Trials Should Proceed Involving Hikma

Hikma does not believe that now is the time to set additional bellwether trials. ***First***, bellwether trial selection is unnecessary because Hikma already participated in substantial discovery in the settled New Mexico litigation, and is party to a number of active state cases across the country, including in Utah, Texas, and West Virginia, and this number is only set to grow: (1) the United States Judicial Panel on Multidistrict Litigation ("JPML") recently concluded that inclusion of "any future actions in MDL No. 2804 is no longer necessary to achieve the just and efficient conduct of the litigation" (ECF No. 9586); and (2) there are approximately 160 cases in the MDL with pending motions to remand to state court that the Court has said it will start addressing in tranches (ECF Nos. 4389, 4502).[3] Adding bellwethers on top of formalized mediation and the potentially growing docket of litigation would overwhelm a party the size of Hikma and have the damaging effect of undermining any settlement efforts.

Second, as explained above, Hikma not only never engaged in any promotional activity, but also has had *de minimis* market share in many jurisdictions and, thus, Hikma does not belong in many of the cases currently pending in the MDL let alone a bellwether. Instead of selecting more bellwethers, Hikma respectfully requests that the Court first allow active settlement tracks, mediations, dismissals, and other processes designed to resolve these matters. Setting bellwethers could potentially undercut mediation or settlement negotiations before they start by overwhelming a defendant of the size and type of Hikma. However, if this Court does decide to select a bellwether

[3] Hikma reserves all defenses and arguments with respect to cases to be included in the MDL and cases proposed for remand.

trial for this set of defendants sometime in the immediate future, Hikma requests an additional 60 days to identify potential bellwether cases. Hikma further requests a chance to resolve certain threshold issues before the bellwethers proceed, including procedural issues regarding service and substantive legal issues regarding generic manufacturers, preemption, injectable products, and addiction therapy products. Hikma will be better positioned to propose appropriate bellwethers once it is able to confirm both the amount and types of cases that will involve Hikma moving forward.

Dated: June 16, 2022

Respectfully submitted,

By: *s/ Christopher B. Essig*

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing instrument was served via the Court's electronic filing system on all counsel of record on June 16, 2022.

s/ Scott M. Ahmad
Scott M. Ahmad